

Attorney Docket No.: **KBI-0022**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/803,211**
Filing Date: **March 18, 2004**
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REMARKS

Claims 1-13 are pending in the instant application. Claims 6-12 have been withdrawn from consideration. Claims 1-5 and 13 have been rejected. Claim 1 has been amended. Claims 3 and 5-13 have been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction

The restriction requirement placing the claims into Groups I-III has been deemed proper and made final. Claims 6-12 have been withdrawn from further consideration. Accordingly, Applicant has canceled claims 6-12 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 3, 5, and 13 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claims 3 and 13 are suggested as being indefinite because the terms "S." and "B." should be spelled out. In addition, claim 5 is suggested to be vague and indefinite for reciting "a selected bacteria" because the neither the claim language nor specification adequately define what Applicant intends "a selected bacteria" to encompass. The cancellation of claims 3, 5, and 13 renders this rejection moot. Therefore, it is respectfully requested that this rejection be withdrawn.

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III. Rejection of Claims under 35 U.S.C. §102

Claims 1-5 have been rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer (U.S. Patent No. 5,501,857). The Examiner suggests that Zimmer teaches a composition comprising bacteria, vitamins and minerals that is encapsulated with gelatin, wherein the bacteria are selected from *Lactobacillus acidophilus*, *L. casei* and/or *Bifidobacterium*. It is suggested that while the reference does not teach that the composition is used for the claimed purpose, the intended use the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition.

Claims 1, 3 and 5 have been rejected under 35 U.S.C. 102(b) as being anticipated by Paul (U.S. Patent No. 5,531,988). The Examiner suggests that Paul teaches a composition comprising *Lactobacillus* and/or *Bifidobacterium*, wherein the bacteria may be *L. acidophilus*, *B. adolescentis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. brevis*, *L. plantarum*, *B. infantis*, *B. longum*, *B. thermophilum*, or *B. bifidum*.

Claims 1-3 and 5 have been rejected under 35 U.S.C. 102(b) as being anticipated by Ford (U.S. Patent No. 5,733,568). The Examiner suggests that Ford teaches compositions comprising *Lactobacillus* bacteria, wherein the bacteria may be *L. acidophilus* or *L. bulgaricus*, and the composition is coated with gelatin. Applicant respectfully disagrees with this rejection.

Claims 1 and 3-5 have been rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Langrehr (U.S. Patent No. 5,785,990). The Examiner suggests that Langrehr teaches

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compositions comprising vitamins, minerals and bacteria selected from *Bifidobacterium*, *L. acidophilus*, and/or *L. casei*.

Claims 1 and 3-5 have been rejected under 35 U.S.C. 102(e) as being anticipated by Halpin-Dohnalek et al. (U.S. Patent No. 5,902,578). The Examiner suggests that Halpin-Dohnalek et al. teach compositions comprising minerals, vitamins, and bacteria selected from *L. acidophilus* or *L. reuteri* and/or *B. infantis*.

Claims 1, 3-5 and 13 have been rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (U.S. Patent No. 6,080,401). The Examiner suggests that Reddy et al. teach compositions comprising probiotics selected from *L. bulgaricus*, *L. acidophilus*, *L. casei*, *S. thermophilus*, *B. bifidus* and/or *B. longum* combined with vitamins and minerals.

Applicant respectfully disagrees with these rejections.

In contrast to the teachings of Zimmer, Paul, Ford, Langrehr, Halpin-Dohnalek et al. and Reddy et al., the instant application teaches in Example 1 (pages 13-16) that a combination of *Lactobacillus acidophilus*, *Streptococcus thermophilus*, and *Bifidobacterium longum* probiotic bacteria, in an amount ranging from 10^9 to 10^{11} colony forming units (see also page 7, lines 25-26), reduce both creatinine and BUN levels in a subject. To highlight these teachings, Applicant has amended claim 1 to recite that the claimed composition comprises *Lactobacillus acidophilus*, *Streptococcus thermophilus*, and *Bifidobacterium longum* probiotic bacteria, wherein said bacteria are in an amount ranging from 10^9 to 10^{11} colony forming units. In light of these amendments, claims 3, 5, and 13 have been canceled to facilitate the prosecution of the instant application. Because Zimmer, Paul, Ford, Langrehr, Halpin-Dohnalek et al. and Reddy et al. fail to

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teach or suggest the claimed composition, these references does not anticipate the instant invention. It is therefore respectfully requested that these rejections be withdrawn.

IV. Double Patenting

Claim 5 has been *provisionally* rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of co-pending Application No. 10/676,622. The cancellation of claim 5 renders this rejection moot. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1-5 and 13 have been *provisionally* rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/676,622.

Claim 1-5 and 13 have been *provisionally* rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 6, 8, and 10 of copending Application No. 10/689,539.

Applicant respectfully requests that these rejections be held in abeyance until allowable subject matter has been identified in these copending applications.

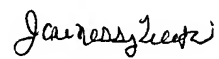
V. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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